

The invention claimed is:

1. An extended release tablet comprising:

(i) a core comprising by weight, based on the core weight, 70 to 99% of metformin, and conventional excipients; and

(ii) a coating consisting essentially by weight, based on the coating weight, of 20 to 85% of a water-insoluble, water-permeable film-forming polymer, of 10 to 75% of a water-soluble polymer and 3 to 40% of a plasticizer,

exhibiting a dissolution profile such that after 2 hours, from 7 to 60% of the metformin is released; after 4 hours, from 15 to 90% of the metformin is released; after 8 hours, from 50 to 100% of the metformin is released; after 12 hours, more than 75% of the metformin is released.

2. The tablet of claim 1, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose.

3. The tablet of claim 1, where the water-soluble polymer is polyvinylpyrrolidone.

4. The tablet of claim 1, where the plasticizer is stearic acid.

5. The tablet of claim 1, where the plasticizer is dibutyl sebacate.

6. The tablet of claim 1, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is stearic acid.

7. The tablet of claim 1, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is dibutyl sebacate.

8. The tablet of claim 1, where the weight proportions water-insoluble, water-permeable film-forming polymer/ water-soluble polymer/plasticizer are 50-85/10-35/3-15.

9. The tablet of claim 1, where the core further comprises an expanding agent, in an amount of 3 to 25%, of the core dry weight.

10. The tablet of claim 9, where the expanding agent is Na starch glycolate.

11. The tablet of claim 9, where the weight proportions water-insoluble, water-permeable film-forming polymer/ water-soluble polymer/plasticizer are 20-50/35-75/15-40.

12. The tablet of claim 1, where the core comprises glyceryl behenate, polyvinylalcohol and silicon dioxide.

13. The tablet of claim 1, exhibiting a dissolution profile such that after 2 hours, from 10 to 40% of the metformin is released; after 4 hours, from 20 to 65% of the metformin is released; after 8 hours, from 50 to 100% of the metformin is released; after 12 hours, more than 75% of the metformin is released.

14. The tablet of claim 1, exhibiting a dissolution profile such that after 2 hours, from 40 to 60% of the metformin is released; after 4 hours, from 65 to 90% of the metformin is released; after 8 hours, from 85 to 100% of the metformin is released; after 12 hours, more than 90% of the metformin is released.

15. An extended release tablet comprising:

(i) a core comprising by weight, based on the core weight, 70 to 99% of metformin, and conventional excipients; and

(ii) a coating consisting essentially by weight, based on the coating weight, of 50 to 85% of a water-insoluble, water-permeable film-forming polymer, of 10 to 35% of a water-soluble polymer and 3 to 15% of a plasticizer;

exhibiting a dissolution profile such that after 2 hours, from 7 to 60% of the metformin is released; after 4 hours, from 15 to 90% of the metformin is released; after 8 hours, from 50 to 100% of the metformin is released; after 12 hours, more than 75% of the metformin is released.

16. The tablet of claim 15, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is stearic acid.

17. The tablet of claim 15, where the core comprises glyceryl behenate, polyvinylalcohol and silicon dioxide.

18. The tablet of claim 15, exhibiting a dissolution profile such that after 2 hours, from 10 to 40% of the metformin is released; after 4 hours, from 20 to 65% of the metformin is released; after 8 hours, from 50 to 100% of the metformin is released; after 12 hours, more than 75% of the metformin is released.

19. The tablet of claim 15, exhibiting a dissolution profile such that after 2 hours, from 40 to 60% of the metformin is released; after 4 hours, from 65 to 90% of the metformin is released; after 8 hours, from 85 to 100% of the metformin is released; after 12 hours, more than 90% of the metformin is released.

20. An extended release tablet comprising:

(i) a core comprising by weight, based on the core weight, 70 to 99% of metformin, an expanding agent and conventional excipients; and

(ii) a coating consisting essentially by weight, based on the coating weight, of 20 to 50% of a water-insoluble, water-permeable film-forming polymer, of 35 to 75% of a water-soluble polymer and 15 to 40% of a plasticizer;

exhibiting a dissolution profile such that after 2 hours, from 7 to 60% of the metformin is released; after 4 hours, from 15 to 90% of the metformin is released; after 8 hours, from 50 to 100% of the metformin is released; after 12 hours, more than 75% of the metformin is released.

21. The tablet of claim 20, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose, the water-soluble polymer is polyvinylpyrrolidone and the plasticizer is dibutyl sebacate.

22. The tablet of claim 20, where the expanding agent represents 3 to 25% of the core dry weight, and is Na starch glycolate.

23. The tablet of claim 20, where the core comprises glyceryl behenate, polyvinylalcohol and silicon dioxide.

24. The tablet of claim 20, exhibiting a dissolution profile such that after 2 hours, from 10 to 40% of the metformin is released; after 4 hours, from 20 to 65% of the metformin is released; after 8 hours, from 50 to 100% of the metformin is released; after 12 hours, more than 75% of the metformin is released.

25. The tablet of claim 20, exhibiting a dissolution profile such that after 2 hours, from 40 to 60% of the metformin is released; after 4 hours, from 65 to 90% of the metformin is released; after 8 hours, from 85 to 100% of the metformin is released; after 12 hours, more than 90% of the metformin is released.

26. The tablet of claim 1, comprising from 400 to 2000mg metformin.

27. The tablet of claim 26, comprising from 550 to 2000mg metformin.

28. The tablet of claim 13, comprising from 550 to 2000mg metformin.

29. The tablet of claim 14, comprising from 550 to 2000mg metformin.
30. The tablet of claim 26, comprising from 400 to 550mg metformin.
31. The tablet of claim 13, comprising from 400 to 550mg metformin.
32. The tablet of claim 14, comprising from 400 to 550mg metformin.
33. The tablet of claim 15, comprising from 400 to 2000mg metformin.
34. The tablet of claim 33, comprising from 550 to 2000mg metformin.
35. The tablet of claim 18, comprising from 550 to 2000mg metformin.
36. The tablet of claim 19, comprising from 550 to 2000mg metformin.
37. The tablet of claim 33, comprising from 400 to 550mg metformin.
38. The tablet of claim 18, comprising from 400 to 550mg metformin.
39. The tablet of claim 19, comprising from 400 to 550mg metformin.

40. The tablet of claim 20, comprising from 400 to 2000mg metformin.
41. The tablet of claim 40, comprising from 550 to 2000mg metformin.
42. The tablet of claim 24, comprising from 550 to 2000mg metformin.
43. The tablet of claim 25, comprising from 550 to 2000mg metformin.
44. The tablet of claim 40, comprising from 400 to 550mg metformin.
45. The tablet of claim 24, comprising from 400 to 550mg metformin.
46. The tablet of claim 25, comprising from 400 to 550mg metformin.